UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,570	09/09/2003	Martin Morrissey	MCA-616 US	5746

25182 7590 01/05/2009

MILLIPORE CORPORATION
290 CONCORD ROAD
BILLERICA, MA 01821

EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
01/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,570	MORRISSEY ET AL.	
	Examiner	Art Unit	
	ELIZABETH L. MCKANE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Padgett (US 4,644,586) or Trewella et al. (US 3,073,507).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven material (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38** adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15. The intended use of the device does not structurally limit the bag in any patentable sense.

As to the recitation of the contents of the bag, it has been held that "expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." See *In re Young,* 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Furthermore, as to the contents and the second section being under a "slight vacuum" or a "slight positive pressure", these limitations are directed to the ultimate intended use of the device and *do not* limit the bag in any structural manner.

As to claims 5 and 6 and the limitations wherein "the bag and its contents being under a slight vacuum" and "the bag and its contents being under a slight positive pressure" are not considered to be structurally limiting on the bag but are intended uses of the bag.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7, 13, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trewella et al. in view of McDonald (US 6,030,578).

Trewella et al. is silent with respect to a closed collar or port attached to the non-porous second section. McDonald, however, discloses a container **201** for sterilizing and transferring articles to a sterile enclosure. The container includes a collar **202** for attachment to a sterile enclosure during transferring of the sterilized articles. This collar is certainly *capable of* use as a pressure or vacuum port, as well. Since the bag of Trewella et al. is disclosed for use in the sterilization of medical articles, it would have been obvious to use the bag of Trewella et al. in the sterile environment of McDonald and when doing so, to provide a collar for connection to the enclosure.

With respect to the port being "for integrity testing", as the port of Trewella et al. with McDonald is certainly capable of being used in such a manner, the limitation has been met.

As to claim 26, this limitation is an attempt to further limit the integrity test, the integrity test having been recited in context of an intended use. Thus, claim 26 does not further limit the apparatus of claim 25.

5. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padgett or Trewella et al., both in view of Wilfinger et al. (US 5,545,841).

Padgett teaches a process for sterilizing a bag **10** having a first porous section **14** and a second non-porous section **12**, and an open end and a closed end. After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-

porous section **12** and bag is sealed **38** adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. also teaches a method for sterilizing a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15.

Neither Padgett nor Trewella et al. disclose a port in the second, sealed section and a step of connecting the port to an integrity tester. Wilfinger et al. teaches that it was known in the art at the time of the invention to apply a vacuum or pressure through a port **17** to the internal space between inner and outer seals of a container in order to establish the integrity of the container and seals. See col.1, lines 35-38; col.6, lines 23-34. The preferred integrity test is a vacuum decay test. See col.7, lines 45-60. Wilfinger et al. teaches that the integrity test is useful in quickly establishing integrity of packages containing sensitive or hazardous materials (col.1, lines 35-38). As Padgett discloses packaging hazardous materials and Trewella et al. teaches packaging sensitive materials, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the integrity test method of Wilfinger et al. in the methods of Padgett or Trewella et al..

Claim Objections

6. Claim 13 is objected to because of the following informalities: the word "and" before "a vacuum" should be deleted. Appropriate correction is required.

Response to Arguments

7. Applicant's arguments filed 22 September 2008 have been fully considered but they are not persuasive.

8. Applicant argues that a "bag with sealed section under vacuum or pressure sufficient to provide a visual indication of integrity in the second non porous section is a structural limitation of the claimed product itself." In response, the Examiner would first note that the instant claims are not written as *product* claims, they are written as apparatus or article claims. There is a distinction given to product claims inasmuch as the contents of the bag are given weight in a product claim. However, as set forth above, the instant claims are not written as product claims, but as article/apparatus claims. Moreover, the Examiner further maintains that the presence of a “slight vacuum” or “slight pressure” within the second section of the bag *is not* a structural limitation of the claim, since the presence of the vacuum or pressure in the second section *only occurs after use* thereof. Thus, it is merely an intended use of the bag and not a structural limitation of the bag.

As set forth in the previous Office Action, Applicant seems to be arguing the limitations of the article of manufacture as illustrated in Figure 2 of the instant invention. If Applicant intends to claim the sealed transfer bag *in combination with* the sterilized

articles located therein, wherein the sealed transfer bag is under pressure or vacuum, then the article of manufacture itself should be claimed. As it stands, the instant claims are either article/apparatus claims drawn to a bag or a process of using the bag.

Certainly it is not patentable to merely pressurize or depressurize the bag of the prior art as this is an ultimate use of the bag itself, not a limitation directed to the structure of the bag. According to Applicant's standard, it would be patentable to take a known Ziplock™ bag, fill it with air, and zip it closed. Clearly, this would not be a patentable invention.

9. As to MacDonald, Applicant argues that one of ordinary skill in the art would not have thought to use the collar of MacDonald to form a vacuum or pressure port since MacDonald is at atmospheric pressure. However, Applicant appears to be reading structure into the term 'vacuum or pressure port' which is simply not in the claims. All that is required by the term 'vacuum or pressure port' is a port that *is capable* of being put into communication with a vacuum or pressure. The apparatus claims *do not require* a source of vacuum or pressure. The port of MacDonald is capable of being put into communication with a vacuum or pressure and Applicant has failed to show that it cannot be. Moreover, the combination with MacDonald results in using the port of MacDonald as a transfer port in the manner disclosed by MacDonald. The port of the combination is not used in connection with a source of vacuum or pressure, not do the claims require such. Thus, although Applicant alleges that the "Office Action hasn't explained why one would use the collar of the reference as a vacuum or pressure port or why one would want to do so," the instant claims *do not require* use of the collar of

MacDonald for a vacuum or pressure port. All that is required is that the port of MacDonald *be capable of* use in the claimed manner, not any teaching to do so.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
31 December 2008